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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/732,848	12/10/2003	Chris Cicenas	END-5006NP	8794

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EXAMINER	
ROY, ANURADHA	

ART UNIT	PAPER NUMBER
3736	

DATE MAILED: 12/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/732,848	CICENAS ET AL.	
	Examiner	Art Unit	
	Anuradha Roy	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 September 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7,28,29 and 32-39* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7,28-33,35-37 and 39* is/are rejected.

7)☐ Claim(s) *34 and 38* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 4 – 7, 30, 31, & 39 are rejected under 35 U.S.C. 102(b) as being anticipated by Hibner et al. (US Patent No. 6,120,462).

With regard to claim 1, Hibner et al. discloses a biopsy device (Figure 1) comprising:

- a hollow biopsy needle (70) having a lateral tissue receiving port (78);
- a hollow cutter (96) advancable within the biopsy needle;
- a first mechanism (Column 4, lines 49-54) for advancing the cutter (96) to a position proximal of the lateral tissue receiving port (78);
- and a second mechanism (Column 4, lines 54-56) for advancing the cutter (96) distal of said position proximal of the lateral tissue receiving port (78).

Regarding claim 4, Hibner et al. discloses a biopsy device, wherein said second mechanism rotates and advances said cutter (Column 4, line 64 - Column 5, line 1).

In regards to claim 5, Hibner et al. discloses a biopsy device, wherein the first mechanism advances the cutter at first rate, and wherein the second mechanism advances the cutter at a second rate (Column 4, lines 46-56). Examiner contends that there are two predetermined translational speeds, thus there are a first rate and second rate.

Regarding claims 6 & 7, Hibner et al. discloses a biopsy device, wherein the first rate is different from the second rate and the first rate is greater than the second rate (Column 3, lines 12-16, 27-35, 47-52 & Column 19, line 36 – Column 20, line 30). Examiner contends the reduction of translational speed in response to the cutting resistance is analogous to the slower second rate, as disclosed by Applicant.

Regarding claim 30, Hibner et al. discloses a biopsy device, wherein the first mechanism is capable of advancing the cutter without the rotation of the cutter, and wherein the second mechanism advances and rotates the cutter (Column 4, lines 64 – Column 5, line 1)

In regard to claim 31, Hibner et al. discloses a biopsy device, wherein the second mechanism advances the cutter from a position proximal of the tissue receiving port to a position distal of the tissue receiving port (Column 4, lines 54 – 56).

In regards to claim 39, Hibner et al. discloses a biopsy device, wherein the second mechanism (Column 4, lines 54-56) is further operable to retract (Column 9, lines 18-23) the cutter from the position distal of the tissue receiving port to the position proximal of the tissue receiving port.

Additional Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 32, 33, & 35-37 are rejected under 35 U.S.C. 102(b) as being anticipated by Miller et al. (US Patent No. 6,758,824).

With regard to claim 1, Hibner et al. discloses a biopsy device (Figure 1) comprising:

- a hollow biopsy needle (27) having a lateral tissue receiving port (25);
- a hollow cutter (17) advancable within the biopsy needle;
- a first mechanism (20) capable of advancing the cutter (17) to a position proximal of the lateral tissue receiving port (25);
- and a second mechanism (22) capable of advancing the cutter 17) distal of said position proximal of the lateral tissue receiving port (25), wherein the second mechanism has at least one component that is not in the first mechanism (22).

In regards to claim 35, Miller et al. discloses a biopsy device, wherein the first mechanism comprises a piston (63).

With regard to claim 36, Miller et al. discloses a second mechanism wherein comprises threaded components with one another (88).

Regarding claim 37, Miller et al. discloses a biopsy device, wherein the second mechanism is operable to simultaneously advance and rotate the cutter (22).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 2 & 3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hibner et al. in view of Miller et al. (US Patent No. 6,638,235).

Regarding claims 2 & 3, Hibner et al. discloses a biopsy device with all of the aforementioned elements. However, Hibner et al. does not disclose a biopsy device, wherein the first mechanism employs a pressure differential or pneumatics for advancing the cutter. Miller et al., however discloses a biopsy device employing pressure differentials and pneumatics (Column 8, lines 1-14). It would have been obvious to one having ordinary skill in the art at the time the invention in view of Miller et

al. to incorporate pneumatics and pressure differentials with Hibner et al. in order to provide a means to drive the cutter.

Additional Claim Rejections - 35 USC § 103

Claims 28 & 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hibner et al. in view of Wright (US Patent No. 4,662,869).

In regard to claims 28 & 29, Hibner et al. discloses a biopsy device with all of the aforementioned elements. However, Hibner et al. does not discloses a biopsy device, where in at least one of the first and second mechanisms comprises a piston and wherein the piston is non-rotating. Wright, however, does disclose a biopsy device, wherein in at least one of the first and second mechanisms comprises a piston (158) and wherein the piston is non-rotating (Column 3, lines 57 – 58). It would have been obvious to one having ordinary skill in the art at the time the invention in view of Wright to incorporate a non-rotating piston with Hibner et al. in order to orient the piston ultimately with the housing (Column 3, line 60 – 62).

Allowable Subject Matter

Claims 34 & 38 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

Applicant's arguments filed September 14, 2006 have been fully considered but they are not persuasive. Applicant asserts Hibner et al. fails to disclose a first and second mechanism for advancing the cutter. Examiner, however, contends the control

signal is a type of mechanism that can have different settings, thus yielding multiple mechanisms. Examiner also notes the definition of mechanism "the fundamental processes involved in or responsible for an action, reaction, or other natural phenomenon" (www.webster.com). Based on this definition, Examiner maintains Hibner et al. anticipates a first mechanism (Column 4, lines 49-54) for advancing the cutter (96) to a position proximal of the lateral tissue receiving port (78); and a second mechanism (Column 4, lines 54-56) for advancing the cutter (96) distal of said position proximal of the lateral tissue receiving port (78).

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case regarding claims 2 & 3, it would have been obvious to one having ordinary skill in the art at the time the invention in view of Miller et al. to incorporate pneumatics and pressure differentials with Hibner et al. in order to provide a means to drive the cutter. Furthermore, in regards to claims 28 & 29, it would have obvious to one having ordinary skill in the art at the time the invention in view of Wright to incorporate a non-rotating piston with Hibner et al. in order to orient the piston ultimately with the housing (Column 3, line 60 – 62). Thus, Examiner maintains the rejections of claims 2, 3, 28 & 29.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anuradha Roy whose telephone number is 571-272-6169 and whose email address is anuradha.roy@uspto.gov. The examiner can normally be reached between 9:00am and 4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

~AR